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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,413	03/01/2004	David M. Anderson	05900010AA	4972

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WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,413	ANDERSON ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-105* is/are pending in the application.

4a) Of the above claim(s) *2,4,15-17,27-82 and 92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-14,18-26 and 83-91,93-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 30-74, 79-80, 82 and 92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 9, 2007. Note claims 79 and 80 are drawn to method.

2. Claims 2, 4, 15-17, 27-29, 75-78, 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 9, 2007.

Applicant's election with traverse of invention group I, in the reply filed on July 9, 2007 is acknowledged. The traversal is on the ground(s) that group I and II should be in one group as invention group II are directed to powder which upon reconstitution form the composition of invention group I. The traverse is persuasive and groups I and II are combined and examined herein.

3. Applicant's election of dantrolene sodium as the medicament in the reply filed on July 9, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Note since dantrolene sodium was elected as the species of *medicament*, claims drawn to medicaments of dantrolene and other active ingredients are considered not read on the elected species and are therefore withdrawn from further consideration.

. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections 35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-8, 10-12, 22, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 5320413 (IDS).

6. JP 5320413 discloses a an dantrolene sodium suspension comprising about 1-50 mg/ml of dantrolene sodium, particular examples disclosed are with a concentration of 1 mg/ml and 5 mg/ml. The composition further comprising carboxylic salt, such as sodium citrate, sodium tartrate, etc. see the entire document, particularly, columns 5-6. As to the limitation of "safe for injection," note since '413 disclosed a pharmaceutical composition, it would have been reasonably expected it is be safe for injection, absent evidence to the contrary. Note, when the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § § 2112- 2112.02. The carboxylic acid salts would meet the limitation of water soluble surfactant. Note, the composition does not have mannitol.

Claim Rejections 35 U.S.C. 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 3, 5-14, 18-26, 83-91, 93-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (IDS), in view of Patel et al. (6,294,192), Ramstack et al. (US 6,495,164), Bosch et al. (US 5,510,118), and JP 5320413(IDS).

9. Ellis teaches dantrolene sodium is an old and well known therapeutical agent, and are known to be administered by any conventional method. The dosage amount is known to be in the range of up to 139 mg/kg of body weight per day. See, particularly, col. 1, lines 10-66, col. 4, lines 1-5.

10. Ellis et al. do not teach expressly the particular composition in high concentration, or be capable of being formulated to a composition in high concentration, or the particular pharmaceutical acceptable carrier and excipients.

11. However, Patel et al. teaches a pharmaceutical composition and method for delivery of hydrophobic therapeutical agents, such as dantrolene sodium, the composition comprise the therapeutical agent, solubilizer, and surfactants, wherein the solubilizer may be alcohols, such as ethylene glycol, propylene glycol, glycerol, polyethylene glycol (PEG 200-600); amide, such as dimethylacetamide, or mixture thereof. The amount of solubilizer is not particularly limited. The composition may be in the form of solution (diluted preconcentrate), semi-solid dispersion, or multiphase dispersion. The composition may be formulated into various forms suitable for

conventional delivery, including oral, topical, transdermal, ocular, parenteral, etc. See, particularly, the abstract, column 24, line 31, col. 25 line 15 to col. 28, line 24, and the claims. For multi-phase dispersion, the solid phase may be in milled, micronized forms. See, particularly, col. 27, lines 11-42. Patel further disclosed that, for dispersion, the particle size is typically less than 20 nm. See, col. 28, line 44 to col. 29, line 4. Ramstack et al. teaches an improved injectable suspension with a concentration of more than 30 mg/ml, wherein the composition is characterized by containing surfactants. See, particularly, the abstract and the claims. Bosch et al. teaches a suspension composition suitable for parenteral administration, comprising water-insoluble nanoparticle therapeutical agent, wherein the average particle sized is about 400 nm and a surface modifier. Suitable surface modifiers include benzalkonium chloride. See, particularly, the abstract, and the claims. JP 5320413 teaches a dantrolene sodium suspension comprising about 1-50 mg/ml of dantrolene sodium, see the entire document, particularly, columns 5-6.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a concentrated dantrolene sodium composition herein by method known in the art, such as incorporate the known pharmaceutical carrier, and/or excipients polyethylene glycol, dimethylacetamide, and/or benzalkonium chloride, either in solution, or in suspension.

A person of ordinary skill in the art would have been motivated to make a concentrated dantrolene sodium composition herein by method known in the art, such as incorporate the known pharmaceutical carrier, and/or excipients polyethylene glycol, dimethylacetamide, and/or benzalkonium chloride, either in solution, or in suspension because dantrolene sodium is known

to be administered up to about 1000 mg per day (for patient with body weight of 75 kg) and make a high concentration composition is apparent for its convenience for administration. Further, concentration up to 50 mg/ml is known in the art. Further, method of making such concentrated composition is known in the art, as evidenced by the cited prior art, one of ordinary skill in the art would have been motivated to make such composition and enjoy a reasonable expectation of success. The employment of the particular combination herein is seen to be a selection from amongst equally suitable material and as such obvious, absent evidence to the contrary. Ex parte Winters 11 USPQ 2nd 1387 (at 1388). Further, The optimization of a result effective parameter, e.g., particle size for an injectable composition, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. As to the dry powder, one of ordinary skill in the art would have been motivated to make a dry powder, which upon reconstitution would yield the solution or suspensions, because of the obvious convenience for storage. As to claims 103-105 which recite steps of simply combining the ingredients and mixing the combination, note such mixing step would have been within the purview of ordinary skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617